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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,838	08/12/1998	OLEG LLIICH EPHSTEIN	0075.0006US1	4128

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EXAMINER	
PESELEV, ELLI	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/117,838	EPHSTEIN, OLEG LLIICH	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-23 and 25-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-23 and 25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2008 has been entered.

Claims 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method of treatment claims 35-37 are indefinite since what is being treated has not been set forth.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17, 19-23, 25-28 and 35-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said composition. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure and combining said substances into a single composition would inherently result in a prior art's composition.

Claim 29 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 3,901,967).

Cohen et al disclose a pharmaceutical composition comprising atropine sulfate. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Claim 30 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirany (U.S. Patent No. 4,987,127).

Sirany discloses a pharmaceutical composition comprising acetylsalicylic acid. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Claim 31 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nobile (U.S. Patent No. 3,134,718).

Nobile discloses a pharmaceutical composition comprising Prednizolon. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Massey et al (U.S. Patent No. 4,839,341).

Masey et al disclose a pharmaceutical composition comprising insulin. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound giving the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Claim 33 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,342).

Jonsson et al disclose a pharmaceutical composition comprising zinc. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Claim 34 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Albert Stock John et al (U.S. Patent No. 3,032,584).

Albert Stock John et al disclose a pharmaceutical composition comprising Sarcolysin. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure. Therefore, the claimed composition would appear to inherently result in a prior art's composition.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant contends that the concept of potentization as extreme dilution is well known in the art. Applicant also contends that the potentiated form of a substance prepared in accordance with the homeopathic technology is a preparation different from just non-potentiated preparation containing a chemically homogeneous substance. These arguments have not been found persuasive. In accordance with the applicant' explanation, the only difference between the pharmaceutically active compound and a potentiated form of said compound is in concentration of said compounds. However, once different concentration of the same compound are combined into a single composition, the resulting composition would contain said pharmaceutically active compound in a single concentration and would inherently be the same as a prior art's composition comprising said active compound.

The declaration by Oleg I. Epstein has also been considered.

The declaration states administration of prednisolone (C30) only did not demonstrate a significant anti-inflammatory effect but that the combined administration with prednisolone resulted in enhanced anti-inflammatory effect and enhanced analgetic potency. However, the declaration fails to state how many rats were treated. Note that the treatment of a single rat does not result in a statistically significant difference of the results obtained. Further, only claim 31 is directed to the prednizolon preparation wherein a therapeutic dose of 1.00 ml prednizolon is impregnated with a 0.005 mg of potentiated prednizolon. Note that the data in the specification fails to test the composition having the claimed amounts of the compounds. Further, it is still not clear how the combination of compositions comprising the same compound at different concentrations is different from a composition comprising said compound.

Also, note that no data has been submitted with respect to atropine, acetylsalicylic acid, insulin and saccolysin encompassed by the present claims. Therefore, the data n the declaration is not commensurate in scope with the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

/Elli Peselev/
Primary Examiner, Art Unit 1623